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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,012	09/14/2001	Colin Gerald Caro	BKY2-0074	7764
7590	07/05/2006		EXAMINER	
Jay F Moldovanyi Fay Sharpe Fagan Minnich & McKee 1100 Superior Avenue 7th Floor Cleveland, OH 44114-2518			PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
				3738

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/857,012	CARO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 April 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 3,5,6,12-16,24-31,44,45 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) 28-31 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 3,5,6,12-16,24-27,44,45 and 47-49 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 13, 2006 has been entered.

***Election/Restrictions***

Claims 28-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 1, 2003.

Claims 28-31 are not drawn to the elected species of Figures 6a to 6c but appear to be drawn to the species of Figure 1a, 1c, and 7-12; these claims have been withdrawn in order to reduce the number of issues for prosecution.

***Claim Objections***

Claim 24 is objected to because of the following informalities: On line 8 of claim 24, the comma after "helical" makes the claim language grammatically awkward. Appropriate correction is required.

***Claim Rejections Based Upon Prior Art***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5, 6, 24-27, 44, and 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by MacGregor (US 5,015,253) as evidenced by Prince (US 5,579,767), and as further evidenced by McGuinness (US 6,156,062), Khosravi et al (US 6,425,915) and Hogan (US 6,569,191). MacGregor anticipates the claim language where it is applied to and in the shape of an aneurysm and an aneurysm is known to produce swirl flow as evidenced by Prince; see Figure 2, column 1, lines 25-55 and column 6, lines 26-43 of MacGregor and see column 2, lines 26-36 of Prince. For this reason, the claim language, pertaining to swirl flow, is considered fully inherently met. The shape and/or orientation of the stent is considered to be non-planar because it is a cylinder. Cylinders are considered to be non-planar curves, to the extent this language can be given patentable weight, because a cylinder is a curved three-dimensional

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shape where no area of its surface in the same plane. Furthermore, the helical centerline is that of the center of a stand (22) and it imparts a corresponding shape to the blood vessel as explained in the following paragraph.

McGuinness (see column 5, lines 53-63), Khosravi (see column 9, lines 47-60), and Hogan (see Figures 8D and 8E as well as column 5, lines 23-30) all provide evidence that stents with helical projections or surfaces embed themselves into the surface of the vessel upon application. For this reason, the Examiner asserts that the stent of MacGregor would also become embedded in the stent wall upon expansion and make an impression thereof on the interior of the stent. Since the stent of MacGregor is at least partially helical, it would inherently impart this at least partially helical shape to the interior of the blood vessel.

Regarding claim 26, Applicants are directed to column 2, lines 21-31, column 4, lines 6-19, and column 6, lines 26-43 where the expanded shape is retained or remembered to the extent that the language "shape memory alloy" can be given patentable weight.

With regard to claim 48, the "generally uniform distribution of fluid flow shear stress" is considered to be quite broad because of the terminology "generally uniform." For this reason, the flow induced by MacGregor is considered to be inherently within the scope of this limitation.

Claims 12-16 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacGregor as applied to claims 3, 5, 6, 24-27, 42 and 44 above, and further in view of Schwartz et al (6,015,387). MacGregor fails to disclose the monitoring device

as claimed. However, Schwartz teaches that such devices were known to the art at the time of the invention; see the abstract and figures. Therefore, it would have been obvious to include a monitoring device in the MacGregor device for the same reasons that Schwartz uses the same and in order to monitor the blood to see if the swirl flow desired is occurring.

With regard to claims 14 and 15, the Schwartz sensor is electrically connected to the power supply and it electromagnetically transmits a signal to a remote monitor, which must have a power supply and recording means to function. This is necessary because the monitor performs a calculation and displays a result; see column 2, lines 25-36. The monitor of Schwartz also uses ultrasound to detect blood flow; see *supra*.

#### ***Response to Arguments***

In response to the traversal of the rejections based upon MacGregor, the Examiner has modified the rejection such that the newly added language requiring at least partial helical centerline has been addressed.

#### ***Allowable Subject Matter***

In order to make the claims allowable over the prior art of record, the Examiner suggests adding the following language to each independent claim (claims 24, 44, 47, and 49) after the last word but before the period:

---wherein the central axis of the hollow tube forms a non-planar three-dimensional helical shape and the hollow tube is capable of imposing said three-dimensional helical shape to the central axis of said vessel---

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Brown et al (US 6,071,305) was considered close prior art because it could be construed as meeting all the limitations of claim 24 except the structure implied by the "whereby" clause at the end of the claim in that it is not seen as capable of inducing swirl flow while imposing a shape. This is due to the fact that it could be used to shape a small vessel into a helical shape if the vessel were slightly larger than the diameter of the elongated tubular member (12) not the diameter of the stent as it is being shown being used; see Figures 2, 7, and 8. However, since the hollow tubular member is filled with substances, it would not be able to induce swirl flow in the blood vessel because fluid could not flow through it along the length thereof. Leone et al and Globermann et al were not considered as close as Brown to reading on the claims because they did not have the capability of inducing swirl flow and/or have openings in the walls as claimed.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic  
Primary Examiner  
Art Unit 3738